JAN 15 2009

510(k) Summary

(As required by 21 CFR 807.92(c))

510(k) Number: K082337

Date Prepared

August 13, 2008

Submitter Information

Submitter's Name:	Vascular Solutions, Inc.
Address:	6464 Sycamore Court Minneapolis, MN 55369
Contact Person:	Julie Tapper Senior Regulatory Affairs Associate Phone 763-656-4228 Fax 763-656-4250

Device Information

Trade Name:	Minnie™ Support Catheter
Common Name:	Percutaneous catheter
Class:	II
Classification Name:	Percutaneous catheter (21 CFR 870.1250, Product Code DQY)

Predicate Devices

Quick-Cross® Support^2 Catheters (K991059, K022138, K033678, and K072750), manufactured by Spectranetics Corporation.

Skyway™ Support Catheter (K052258 and K060327), manufactured by Vascular Solutions, Inc.

Device Description

The Minnie Support Catheter is available in nine models. A summary of the nine models is provided in the following table:

Model Number	Guidewire Compatibility	Working Length	Proximal OD	Distal OD
5700	.014"	135cm	0.0390"	0.0260"
5701	.014"	150cm	.0390"	.0260"
5702	.018"	90cm	.0440"	.0300"
5703	.018"	135cm	.0440"	.0300"
5704	.018"	150cm	.0440"	.0300"
5705	.035"	65cm	.0630"	.0500"
5706	.035"	90cm	.0630"	.0500"
5707	.035"	135cm	.0630"	.0500"
5708	.035"	150cm	.0630"	.0500"

Each Minnie catheter is a single lumen polyethylene tube that comprises the catheter shaft. To create a lower crossing profile, the shaft tapers at the distal end. A polyethylene hub is overmolded onto the shaft and each catheter has a printed strain relief component that is just distal of the hub. To confirm position and aid in estimating geometries in the vasculature, each device has three evenly-spaced, radiopaque marker bands at the distal end—the distal-most marker band is approximately 2.5mm from the distal tip. The 5700 and 5701 models have printed-positioning markers at 95cm and 105cm from the distal tip. A hydrophilic coating is applied to the distal-most 40cm of the shaft to provide a lubricious outer surface. Each Minnie catheter is compatible with ≥5F introducer sheaths and ≥6F guide catheters.

The Minnie catheter is provided sterile and intended for a single-patient use.

Intended Use/Indications for Use

The Minnie support catheters are intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. The Minnie support catheters also may be used to subselectively infuse/deliver therapeutic agents.

Summary of Non-clinical Testing

Bench testing was conducted on the Minnie catheter, and included an assessment of the physical properties of the device and its ability to achieve its intended use. The results of the tests confirmed the suitability of the device for its intended use. Each bench test that was conducted is listed, below.

Visual inspection for sharp edges	Corrosion resistance
Radiopacity	Positioning marker integrity
Hydrophilic coating (lubricity)	Torque strength
Visual inspection for excessive hydrophilic coating	Dynamic pressure
Hydrophilic coating integrity	Static pressure
Hydrophilic coating integrity—Congo Red Dye	Distal outer diameter measurement
Tortuosity	Marker band spacing
Kink resistance	Hub luer compliance
Flow rate	Guidewire compatibility
Hub-to-shaft bond strength	Guide catheter compatibility
Distal shaft strength	Introducer sheath compatibility
Liquid leak under pressure	Temperature and humidity conditioning
Air leak during aspiration	

Summary of Clinical Testing

Clinical evaluations were not required for this device.

Statement of Equivalence

The Minnie catheter is substantially equivalent to the currently marketed Quick-Cross and Skyway catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods.

Conclusion

The Minnie catheter is substantially equivalent to the currently marketed Quick-Cross and Skyway catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vascular Solutions, Inc.
c/o Ms. Charmaine Sutton
6464 Sycamore Court
Minneapolis, MN 55369

JAN 15 2009

Re: K082337
Trade/Device Name: Minnie™ Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 26, 2008
Received: December 1, 2008

Dear Ms. Sutton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K082337

Device Name:

Minnie™ Support Catheter

Indications for Use:

The Minnie support catheters are intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. The Minnie support catheters also may be used to subselectively infuse/deliver therapeutic agents.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Lines

(Division Sign-Off)
Division of Cardiovascular Devices

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